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SCREENING AND SURVEILLANCE – PRINCIPLES AND PRACTICE

RJC Steele

Abstract

Health screening can only be applied to populations, not individuals. For it to be effective, the initial screening test must be acceptable and reasonably accurate, the disease must be treatable with better outcomes when treated early and the harm and cost associated with screening must not outweigh its benefits. Robust evidence is therefore required before systematic screening is implemented. Surveillance implies the testing of people at high risk of disease and is therefore distinct from screening in both scale (smaller) and intensity (greater). In both cases, however, clear information must be provided to potential participants so that they can weigh up the balance of benefit and harm before deciding on whether or not to engage in the process.

Article

The term “screening” derives from the practice of sieving gravel from a river bed to remove the majority of small particles so that larger nuggets of gold are more easily identified. Thus, health screening implies testing a large number of asymptomatic individuals with a view to detecting a small number with early disease or risk of developing disease in order to improve the outcome. It follows that only populations can be screened – individuals can only be tested. Criteria for effective screening were set out by Wilson and Jungner in the 1960’s,¹ and these are encapsulated in the following three statements:

1. There is a screening test that is acceptable to those for whom it is intended, which is reasonably accurate and can be offered to large numbers of appropriate people.
2. The disease in question is not only treatable, but, in addition, treatment of disease at an early stage of its development produces better outcomes than treating disease that presents with symptoms.
3. The harm and cost associated with detecting and treating early disease by screening is less than the harm and cost of not screening for the disease. This should not be taken to mean that screening must necessarily save money, it implies cost-effectiveness; i.e. any improvement in quality and/or quantity of life

must not come at a cost that society cannot sustain both in terms of actual resource and physical or psychological harm created by offering screening

To be absolutely sure that these principles apply to a specific disease process, particularly in adult screening, it is essential to carry out population based randomised controlled trials (RCTs) where a target population is randomly divided into two groups: one is actively invited for screening and the other forms an uninvited control group. The outcomes from the disease are then analysed on an intention to screen basis, i.e. the group invited to screening must include those who have chosen not to participate and those who are diagnosed with the disease after a negative screening test (interval disease) as well as those who are screened and who may have screen-detected disease. The purpose of adopting this rigorous and intensive approach is to remove the effect of important biases that are part and parcel of the whole process of screening².

Perhaps the most obvious bias is lead-time; as the duration of survival from a disease has to be measured from the time of diagnosis, screening always appears to improve mortality by lengthening the interval between diagnosis and death without necessarily affecting the actual time that death was destined to occur. Another important issue is volunteer bias; when a population is invited for screening, some, often a significant proportion, will not participate. The reasons for this are various, but overall, those who do not participate in screening are, in general, more deprived and less healthy than those who do, and thus will have poorer outcomes from any disease process, including that being screened for. This, of course, artificially enhances the benefit of screening. Length bias occurs as screening tends to pick up relatively slow-growing disease. Finally, over-diagnosis introduces bias since screening will inevitably detect disease that is not destined to cause suffering or death because the lead time is so long that some of those diagnosed by screening will have died from other causes before the disease would have caused symptoms.

Well-conducted population-based RCTs will eliminate the inherent biases, but this in itself is not sufficient evidence to be certain that screening should be recommended. Even if disease-specific mortality or morbidity is shown unequivocally to be reduced by screening, it is still possible for screening to cause more harm than good or require too much resource to be sustainable. Thus, in addition to RCTs, careful cost-benefit analyses are required in order to satisfy the third principle summarised above.

A good example of this is prostate cancer screening, where there is RCT evidence of mortality reduction³, but the price of preventing one prostate cancer death is treating 27 men needlessly and causing significant morbidity. For the reason, the UK National Screening Committee, which is responsible for advising the UK governments on screening policy⁴, has not recommended population screening for this disease⁵. In breast cancer, overdiagnosis occasioned by the mammographic detection of ductal

carcinoma in situ (DCIS) has called breast cancer screening into question on several occasions⁶.

There is a so called screening paradox whereby the benefits are more apparent than some of the downsides. Most people have a negative screening test and get the “all clear”. Only a tiny proportion of the screened population will experience adverse effects from anxiety or treatment for disease that would not have caused any symptoms or harm. Most of these people will be unaware that this was the case and may even be grateful to the system that has “saved” them.

It is also possible that changes in the impact of a disease may change with time; treatments may improve so much that the benefit of early detection is lessened, and prevention strategies may reduce the incidence of the disease so much that screening is no longer useful or viable. An example of the latter is vaccination for HPV, which may, with time, make cervical screening redundant.

It is therefore really important that new screening programmes are not initiated without rigorous assessment of the evidence, and that existing programme are kept under regular review. By ensuring that only clinically beneficial and cost-effective screening is prosecuted, causing unintended harm and spending large amounts of money to no good effect can be minimised.

The distinction between screening and surveillance is a grey and difficult area. In the end, however, it requires a pragmatic approach to ensure that, whichever label is attached to a process, some body takes ownership of it and adopts an evidence-based approach to its implementation (or not) as articulated above. For practical purposes, however, screening can be defined as the process of actively approaching large numbers of asymptomatic people, most of whom will be free of disease, and offering them testing that is either diagnostic for the disease in question or that can identify a high-risk group that can then be offered diagnostic investigations. Responding to a need for testing because of a very high-risk condition (e.g. Lynch syndrome⁷ or BRCA⁸ carriers) can be defined as surveillance as it does not involve pro-actively identifying the high-risk individuals from within an average risk population. It is the remit of the UK NSC to advise on screening, and of other bodies, notably the National Institute for Health and Care Excellence (NICE)⁹, to advise on surveillance. None of this is set in stone, however, and it is critical to have dialogue between the responsible organisations to ensure that the needs of patient groups and the population as a whole are met and do not fall between two stools.

Offering screening is very different from offering treatment to a symptomatic patient. When discussing diagnostic and treatment options for a disease, a clinician has a very clear duty to explain both the benefits and the potential complications of that treatment so that the patient can make a decision based on this information, i.e. so that they can make an informed choice. In responsible medical practice, this has always been true, although it was emphasised by the “Montgomery” ruling¹⁰, when it was clarified that

information given to a patient to help them come to a decision about treatment options should be that required by any reasonable patient rather than it being in the domain of a reasonable body of medical opinion.

When screening is offered, there can be public emphasis on the virtues of participating despite the fact that the chances of an individual benefiting are much less than they would be when being treated for an established disease process. High coverage uptake is important in population screening in order to make an impact on the burden of disease on society, and hence there is well-meaning reluctance to discuss or explain the possible adverse effects of participating in screening. However, if there is a duty of candour for treatment, where the likelihood of benefit is high for an individual, then there must be a similar duty for screening where the likelihood of benefit is lower. Thus, one of the main challenges in screening is to balance the need for sufficiently high participation rates to have a meaningful impact on the disease with the need to provide transparent information to people so that they can make an informed choice about whether or not to participate in screening.

In conclusion, screening has the potential to do good, but it also does harm. All stakeholders have a responsibility to ensure that screening programmes do more good than harm and at reasonable cost. This requires constant re-evaluation of evidence and generation of new knowledge as well as vigilance relating to the quality and delivery of existing programmes. Screening and surveillance are not the same, but they are related and it is essential that they are both based on firm evidence. Finally, informed choice is a cornerstone of ethical screening and requires careful and sensitive communication with individuals and the population.

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